

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: AVANDIA MARKETING, SALES	:	MDL NO. 1871
PRACTICES AND PRODUCTS	:	07-MD-01871
LIABILITY LITIGATION	:	
		HON. CYNTHIA M. RUFÉ
THIS DOCUMENT APPLIES TO:	:	CIVIL ACTION
	:	
Amjad Faheem v. GlaxoSmithKline, LLC	:	No. 11-695
Marvin Rainey v. GlaxoSmithKline, LLC	:	No. 11-3031

Rufe, J.

August 7, 2012

Plaintiffs in these cases filed suit alleging that they suffered heart-related injuries caused by their ingestion of the drug Avandia. Defendant, GlaxoSmithKline, LLC (“GSK”), has filed motions for summary judgment, contending that Plaintiffs’ claims are barred by the applicable statutes of limitations.¹ Plaintiffs, through the Plaintiffs’ Steering Committee (“PSC”), oppose the motions and have moved for additional discovery pursuant to Federal Rule of Civil Procedure 56(d).²

I. BACKGROUND

Plaintiff Marvin Rainey, a resident of Tennessee, began using Avandia in 1999 and suffered a heart attack in 2000; Plaintiff Amjad Faheem, a resident of Kentucky, began using

¹ GSK filed the Motion for Summary Judgment in five cases. By notice dated February 28, 2012, GSK withdrew the motion in the case of Randall v. GlaxoSmithKline, LLC, Civil Action No. 10-4861, as the case became subject to a pending settlement agreement. By letter dated June 6, 2012, GSK advised the Court that an agreement in principle had been reached to settle the cases of Bonn v. GlaxoSmithKline, LLC, Civil Action No. 11-2734, and Estate of Henry v. GlaxoSmithKline, Civil Action No. 10-4080.

² By Memorandum and Order dated September 7, 2011, the Court denied motions to dismiss based on the statute of limitations in 60 cases. Defendant GlaxoSmithKline, LLC (“GSK”) filed motions for partial reconsideration, seeking again to dismiss all or part of 49 of these cases; those motions were also denied. In the earlier rulings, the Court held that the Court could not make a determination in the context of a motion to dismiss, but required an evidentiary record.

Avandia in 2001 and suffered a heart attack in 2004. Both Plaintiffs filed suit in 2011, alleging that their use of Avandia caused their injuries. Avandia, the brand name for rosiglitazone maleate, was approved by the Food and Drug Administration in 1999 and is manufactured by Defendant GSK. Avandia is a member of a class of drugs known as thiazolidinediones (“TZDs”), used to manage non-insulin-dependent diabetes, or Type 2 diabetes.

Defendant GSK seeks summary judgment on the statute of limitations as to these two Plaintiffs, but also seeks significantly broader relief. Specifically, GSK seeks to establish a “bar date,” i.e., the date by which any plaintiffs may be presumed as a matter of law to have been on notice of a possible link between Avandia and their injuries, and therefore to pursue any tort claims. GSK argues that for plaintiffs alleging heart-related injuries from use of Avandia, the bar date is November 14, 2007.

II. STANDARD OF REVIEW

Upon motion of a party, summary judgment is appropriate if “the materials in the record” show “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”³ Summary judgment may be granted only if the moving party persuades the district court that “there exists no genuine issue of material fact that would permit a reasonable jury to find for the nonmoving party.”⁴ A fact is “material” if it could affect the outcome of the suit, given the applicable substantive law.⁵ A dispute about a material fact is “genuine” if the evidence presented “is such that a reasonable jury could return a verdict for the

³ Fed. R. Civ. P. 56(a), (c)(1)(A).

⁴ Miller v. Ind. Hosp., 843 F.2d 139, 143 (3d Cir. 1988).

⁵ See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

nonmoving party.”⁶

In evaluating a summary judgment motion, a court “must view the facts in the light most favorable to the non-moving party,” and make every reasonable inference in that party’s favor.⁷ Further, a court may not weigh the evidence or make credibility determinations.⁸ Nevertheless, the party opposing summary judgment must support each essential element of the opposition with concrete evidence in the record.⁹ “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.”¹⁰ This requirement upholds the “underlying purpose of summary judgment [which] is to avoid a pointless trial in cases where it is unnecessary and would only cause delay and expense.”¹¹ Therefore, if, after making all reasonable inferences in favor of the non-moving party, the court determines that there is no genuine dispute as to any material fact, summary judgment is appropriate.¹²

Plaintiffs have filed a motion for additional discovery pursuant to Rule 56(d), which is “the proper recourse of a party faced with a motion for summary judgment who believes that

⁶ Id.

⁷ Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005).

⁸ Boyle v. County of Allegheny, 139 F.3d 386, 393 (3d Cir. 1998).

⁹ Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986).

¹⁰ Anderson, 477 U.S. at 249-50 (citations omitted).

¹¹ Walden v. Saint Gobain Corp., 323 F. Supp. 2d 637, 641 (E.D. Pa. 2004) (citing Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976)).

¹² Celotex, 477 U.S. at 322; Wisniewski v. Johns-Manville Corp., 812 F.2d 81, 83 (3d Cir. 1987).

additional discovery is necessary before he can adequately respond to that motion.”¹³ A properly filed motion must be accompanied by “a supporting affidavit detailing what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained.”¹⁴

III. DISCUSSION

A. Applicable Law

The rules of the Judicial Panel on MultiDistrict Litigation allow cases to be filed directly in this District and made part of the Avandia MDL, which Plaintiffs in these cases did.¹⁵ The Court must determine whether to apply Pennsylvania law or the law of Plaintiffs’ home states. The Court has concluded, as have other MDL courts, that such cases should be governed by the law of the states where Plaintiffs received treatment and prescriptions for Avandia.¹⁶ This ruling will promote uniform treatment between those Plaintiffs whose cases were transferred into the MDL from their home states and those Plaintiffs who filed directly into the MDL. This holding is also consistent with Pennsylvania’s choice-of-law rules, because “Pennsylvania applies a flexible rule which permits analysis of the policies and interests underlying the particular issue

¹³ Murphy v. Millennium Radio Grp. LLC, 650 F.3d 295, 309 (3d Cir. 2011). Rule 56(d) provides that “[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order.”

¹⁴ Doe v. Abington Friends Sch., 480 F.3d 252, 257 n.3 (3d Cir. 2007) (internal quotation omitted).

¹⁵ JPML Rule 7.2(a) provides that “[p]otential tag-along actions filed in the transferee district do not require Panel action. A party should request assignment of such actions to the Section 1407 transferee judge in accordance with applicable local rules.”

¹⁶ See, e.g., In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-MD-2100, 2011 WL 1375011, *5 (S.D. Ill. Apr. 12, 2011) (holding that cases that originated outside of the court’s judicial district and that were filed directly into the MDL would be treated as if they were transferred from a judicial district sitting in the state where the case originated).

before the court and directs courts to apply the law of the state with the ‘most interest in the problem.’”¹⁷ In personal injury cases, that is the state where the injury occurred.¹⁸

Faheem’s home state, Kentucky, employs a one year statute of limitations for personal injury cases.¹⁹ Kentucky law also recognizes the “discovery rule,” under which “[a] cause of action will not accrue . . . until the plaintiff discovers or in the exercise of reasonable diligence should have discovered not only that he has been injured but also that his injury may have been caused by the defendant's conduct.”²⁰ Reasonable diligence requires that the plaintiff be “as diligent as the great majority of persons would [be] in the same or similar circumstances”²¹

Rainey’s home state, Tennessee, also has a one-year statute of limitations in personal injury cases,²² with the cause of action generally accruing on the date of the injury.²³ Tennessee

¹⁷ Specialty Surfaces Int’l v. Cont’l Cas. Co., 609 F.3d 223, 229 (3d Cir. 2010).

¹⁸ See, e.g., Flamer v. New Jersey Transit Bus Operations, Inc., 607 A.2d 260, 264 (Pa. Super. Ct. 1992) (internal citation omitted). The Court does note that Pennsylvania has a “borrowing statute,” which provides that “[t]he period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, whichever first bars the claim.” 42 Pa. Cons. Stat. Ann. § 5521(b). However, because the Court considers that “direct filed” cases should be treated as if they were filed in the Plaintiffs’ home states, the forum-shopping concerns of this statute are not implicated here.

¹⁹ See Ky. Rev. Stat. § 413.140(1), (1)(a).

²⁰ R.T. Vanderbilt Co., Inc. v. Franklin, 290 S.W.3d 654, 659 (Ky. Ct. App. 2009) (citing Louisville Trust Co. v. Johns–Manville Prods. Corp., 580 S.W.2d 497, 501 (Ky. 1979) (quotation in Louisville Trust omitted)); see also Johnson v. Sandoz Pharm. Corp., 24 F. App’x 533, 535-39 (6th Cir. 2001) (applying Kentucky law in determining how the discovery rule affected the statute of limitations in products liability case where plaintiff claimed Parlodel led to stroke).

²¹ Id. (citing Blanton v. Cooper Indus., 99 F. Supp. 2d 797, 802 (E.D. Ky. 2000) (quoting Sawyer v. Midelfort, 595 N.W.2d 423, 439 (Wis. 1999)) (internal quotations omitted)).

²² See Tenn. Code Ann. § 28-3-104(a), (a)(1) (“Actions for . . . injuries to the person” “shall be commenced within one (1) year”).

²³ Tenn. Code Ann. § 28-3-104(b)(1).

also recognizes the discovery rule which tolls the statute of limitations until “one discovers, or in the exercise of reasonable diligence should have discovered, both (1) that he or she has been injured by wrongful or tortious conduct and (2) the identity of the person or persons whose wrongful conduct caused the injury.”²⁴ This only requires that the plaintiff be aware of those facts sufficient “to place a reasonable person on notice that the injury was the result of the wrongful conduct of another.”²⁵

B. 2007 Evidence of a Possible Link between Avandia Use and Heart-Related Injuries

1. The Nissen Study and FDA Action

After conducting a meta-analysis study, Dr. Steven Nissen concluded that use of Avandia was associated with an increased risk of heart attack. Specifically, the Nissen study found that Avandia increased the risk of myocardial infarction by 43%, a statistically significant result.²⁶ The New England Journal of Medicine published the peer-reviewed Nissen study on May 21, 2007. In response to the Nissen study’s publication, the American College of Cardiology, American Diabetes Association, and American Heart Association issued a statement expressing concern and advising patients with diabetes to speak with their physicians.²⁷ At a meeting in July

²⁴ Sherrill v. Souder, 325 S.W.3d 584, 595 (Tenn. 2010). See also Wyatt v. A-Best, Co., Inc., 910 S.W.2d 851, 854 (Tenn. 1995); Potts v. Celotex Corp., 796 S.W.2d 678, 680-81 (Tenn.1990) (“[T]he statute [of limitations] is tolled only during the period when the plaintiff had no knowledge at all that the wrong had occurred and, as a reasonable person, was not put on inquiry.”); Teeters v. Currey, 518 S.W.2d 512, 512-17 (Tenn. 1974) (first adopting the discovery rule); Carter v. Danek Med, Inc., 1999 WL 33537317, at *3-4 (W.D. Tenn. 1999) (discussing the tolling of the statute of limitations in products liability claims involving spinal surgery).

²⁵ Id.

²⁶ In re Avandia, No. 07-1871, 2011 WL 13576, at *3 (E.D. Pa. Jan. 4, 2011).

²⁷ GSK Ex. 138.

2007, the Food and Drug Administration Advisory Committee voted 20-3 that “available data support a conclusion that Avandia increases cardiac ischemic risk,” but did not act at that time to restrict the availability of Avandia.²⁸ However, the FDA did require that GSK revise the product label for Avandia, and GSK agreed to include within a black box warning the statement that “Avandia was not recommended for any patient with symptomatic heart failure,” to add a summary of the results of an integrated data set from 42 clinical trials regarding risk of myocardial ischemic events, and to include more detailed results in the Warnings section in the label.²⁹

2. “Dear Healthcare Professional” and “Dear Patient” Letters

From May through November 2007, GSK sent a series of letters to healthcare professionals regarding studies of Avandia and cardiovascular health.³⁰ These letters discussed various studies, including the Nissen study (and GSK’s disagreement with it)³¹ as well as regulatory developments with regard to cardiovascular risk and Avandia use, culminating in a November 2007 letter reporting on the label revision. Any physician receiving these letters would be aware that there was concern about cardiovascular health and use of Avandia, although the letters expressed GSK’s view that Avandia remained “an important treatment option for physicians” in treating diabetes.³² On June 1, 2007, GSK also published a “Dear Avandia

²⁸ PSC Ex. 124 at 4.

²⁹ GSK Ex. 137.

³⁰ GSK Exs. 130-37.

³¹ GSK Ex. 130 at 1.

³² E.g., GSK Ex. 137 at 2.

Patient” letter, which responded to the “recent press coverage about the safety of Avandia” and stated that GSK stood firmly behind Avandia.³³ Plaintiffs have produced evidence that during this same time frame, GSK criticized the Nissen study, and worked to encourage physicians to continue to prescribe Avandia.³⁴

3. Media Reports

The publication of the Nissen Study generated substantial interest in the media. Significantly, in the days following the publication, television news programs highlighted the findings of the Nissen report, in several instances as the lead story on the national evening broadcast.³⁵ These reports summarized the findings of the Nissen study and also noted that GSK “strongly disagrees with the conclusions . . . and says other studies prove the drug’s safety.”³⁶ During the summer and fall of 2007, national and local newspapers published articles of varying depth and prominence discussing reported risks of Avandia use.³⁷ Many of these news reports included GSK’s assurances that Avandia was safe and effective. The media also reported the actions of the FDA Advisory Committee, describing it in at least one report as sending a “mixed message” to Avandia patients.³⁸ The November 2007 label revision generated still more news

³³ Compls. ¶ 55.

³⁴ PSC Exs. 134-42.

³⁵ GSK Exs. 9-19.

³⁶ See, e.g., GSK Ex. 9.

³⁷ GSK Exs. 20-142. GSK also produced a listing of news reports that mentioned Avandia. GSK Exs. 5-6. The Court finds these exhibits of limited use to the Court; a number of the references appear to be to articles mentioning the effect of Avandia issues on GSK’s stock price, for example, and do not appear likely to have drawn general notice.

³⁸ GSK Ex. 82 (ABC News transcript, July 31, 2007).

stories, which included the information that the FDA had decided to keep Avandia on the market and noted that the evidence of an increased risk of cardiovascular events was “inconclusive.”³⁹

C. The Cumulative Effect of 2007 Events Triggered the Duty to Investigate

The evidence shows that the events described above were regarded as significant by physicians, patients, and attorneys. By August 2007, Avandia prescriptions had fallen by 45%; by November 2007, sales had fallen 54%.⁴⁰ This MDL was formed in 2007 as a result of numerous lawsuits filed nationwide that year.

The question then becomes, did all of these events suffice, as a matter of law, to put on notice those who had suffered heart-related injuries that Avandia could be to blame and trigger a duty to investigate? The extensive media reports “indicate what was in the public realm at the time, not whether the contents of those articles were in fact true.”⁴¹ What was in the public realm throughout the second half of 2007 linked Avandia use with the possibility of heart-related illness, although the reports certainly did not reach an unqualified conclusion in that regard.⁴²

The Court concludes that a reasonable person who knew that he or she had suffered cardiovascular injury and had taken Avandia would have been put on notice by the end of 2007 of the need to investigate a possible link between Avandia and the injury. Plaintiffs argue

³⁹ See, e.g., GSK Ex. 121 (New York Times article, Nov. 15, 2007).

⁴⁰ PSC Ex. 128; GSK Rao Decl. Ex. 4.

⁴¹ Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Management L.P., 435 F.3d 396, 401 n.15 (3d Cir. 2006).

⁴² Other Courts have set similar limitations periods. See, e.g., In re Briscoe, 448 F.3d 201, 220-21 (3d Cir. 2006) (in diet drugs litigation, finding that the statute of limitations barred claims after class notifications that followed withdrawal of the drugs from the market); In re Vioxx Prods. Liab. Litig., 522 F. Supp. 2d 799, 803 (E.D. La. 2007) (finding that the statute of limitations barred claims after extensive publicity following the withdrawal of Vioxx from the market). Other courts have found that the statute of limitations applies even when a drug has not been withdrawn from the market. See, e.g., In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230 (E.D.N.Y. 2007).

strenuously that GSK concealed information regarding the risks of Avandia and continued to downplay the seriousness of the risks until 2010, and that in August 2007, GSK argued to physicians that the “totality of evidence” showed “[n]o increased risk of [cardiovascular events] vs. oral antidiabetic agents.”⁴³ Accepting Plaintiffs’ argument as true for purposes of the motions for summary judgment, Plaintiffs in these cases *had already suffered heart attacks, and knew that they had done so*. A reasonable person who had suffered a heart attack, and who had taken Avandia, as Plaintiffs here did, would have been on notice by the end of 2007 to investigate a possible link between the Avandia use and the heart attack.⁴⁴ Similarly, Plaintiffs’ arguments of fraudulent concealment miss the mark. The issue of whether GSK should have disclosed more information or disclosed it sooner does not affect what information became available in 2007.

D. Plaintiffs’ Rule 56(d) Motion

Plaintiffs have moved for time to take additional discovery, including individualized discovery as to what Plaintiffs and their physicians knew and when, and extensive discovery that essentially relates to GSK’s alleged fraudulent concealment. The Court finds that these are not typical cases where summary judgment is sought before discovery: during the course of the MDL, many hundreds of thousands of pages of documents have been produced, and Plaintiffs have not demonstrated that more is necessary on the issues discussed herein. Further, discovery as to the personal circumstances of Plaintiffs is not required because the evidence presented

⁴³ PSC Ex. 126.

⁴⁴ The Court notes that Type 2 diabetes is not a temporary condition; there is no cure, and patients who were receiving treatment in 2000 would still need to be managing their condition in 2007 (although not necessarily with medication). See Mayo Clinic Staff “Type 2 Diabetes” retrieved from <http://www.mayoclinic.com/health/type-2-diabetes/DS00585> (last viewed Aug. 1, 2012).

demonstrates as a matter of law that the information available both to the general public and to treating physicians throughout 2007 should have put a reasonable person on notice to investigate the possible link between a heart attack already suffered and use of Avandia.⁴⁵

E. Limitations of the Court's Ruling

The Court holds that under the laws of Tennessee and Kentucky, a reasonable person who knew that he or she had suffered a heart-related injury after taking Avandia was on notice by the end of 2007⁴⁶ to investigate the possibility of a link between Avandia and their injury so as to start the statute of limitations running on tort claims alleging personal injury. This ruling does not address Avandia patients who suffered other injuries, such as stroke; nor does it address any other claims asserted against GSK. The Court is not ruling at this time on whether GSK concealed evidence of the risks of Avandia use. The Court also notes that the law of certain states may have a different view of when a claim is tolled.

IV. CONCLUSION

The Court holds that a reasonable person who knew that he or she had suffered a heart-related injury after taking Avandia was on notice to investigate the possible link between the injury and Avandia use by December 31, 2007. Because Plaintiffs did not file their personal-injury claims within the applicable statute of limitations, GSK's Motions for Summary Judgment will be granted, and those claims will be dismissed. An appropriate order will be entered.

⁴⁵ In addition, Plaintiffs were not prevented from offering evidence of their individual circumstances, for example, through affidavits.

⁴⁶ Although GSK argues that the bar date should be November 14, 2007, the Court finds that news coverage of the 2007 label revision continued after that date, and therefore concludes that the last date on which Plaintiffs should have been on notice is December 31, 2007.